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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,090

Applicant(s)

HAREL, MOTI

Examiner

Kevin S. Orwig

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-123 is/are pending in the application.
- 4a) Of the above claim(s) 101, 102, and 117-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-100, 103-116, and 121-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendments filed on Oct. 13, 2009 have been entered.

Status of the Claims

Claims 87-123 are pending. Claims 87, 100, 103, 117, 118, and 121 have been amended; claims 1-86 are cancelled; claims 101, 102, and 117-120 are withdrawn. Claims 87-100, 103-116, and 121-123 are now under consideration. This Office Action is in response to the request for continued examination filed on Nov. 12, 2009.

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to claim 103 is withdrawn in light of the claim amendments.

The rejection of claims 87-96, 98, 103, 104, 108-112, and 114 under 35 U.S.C. 103(a) over KÜRZINGER and NAKATSUKA is withdrawn in favor of the analogous rejection adding TESTER as discussed below.

The rejection of claims 87, 97-100, 103, 105-107, 113, 115, 116, and 123 under 35 U.S.C. 103(a) over KÜRZINGER, NAKATSUKA, and VILLAMAR is withdrawn in favor of the analogous rejection adding TESTER as discussed below.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claim 95 under 35 U.S.C. 112, 1st paragraph, lack of written description, is maintained as discussed below.

The rejection of claim 95 under 35 U.S.C. 112, 2nd paragraph is maintained, as discussed below.

The rejection of claims 121 and 122 under 35 U.S.C. 102(b) is maintained as discussed below.

Claim Rejections - 35 USC § 112 (1st Paragraph) (Maintained)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Specifically, claim 95 recites "starch derivatives".

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106). See MPEP § 2163.

Applicant has failed to provide any further description of the various "derivatives" as recited in instant claim 95 that would provide adequate written description of the compounds encompassed by the claim. Adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties. Applicants provide no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful to form a controlled-release particle with alginate. The term "derivatives" is extremely broad and encompasses, for example, salt forms, reaction products, and degradation

products. It is noted that in the present case, no examples of the claimed derivatives are provided or described. In fact, starch derivatives are not mentioned in the specification at all. Thus, the artisan would have no guidance from the instant disclosure. The skilled artisan would have been unable to readily envision all of the chemical structures intended to be encompassed by the claimed subject matter (i.e. the entire genus encompassed by the claim). Thus, the disclosure fails to describe the claimed compounds in a manner that complies with the written description requirement of 35 U.S.C. 112, 1st Paragraph.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive. Applicant submits a reference to support the allegation that "starch derivatives" were well-known in the art (response, p. 6).

The reference submitted by applicant supports the Office's position. For example, the reference states, "Countless starch derivatives have been described in technical literature and in patents..." (p. 695 of the reference). This breadth is precisely why the 112 1st paragraph rejection was made, in conjunction with the fact that starch derivatives are not mentioned in the specification at all, no examples were given, and no indication whatsoever was provided to lead an artisan to only the subset of starch derivatives useful in the present invention. As evidenced by applicant's own reference, the scope of the term "derivatives" goes far beyond the starches manufactured and used commercially, hence the written description rejection. It is reiterated that no examples of starch derivatives were presented or even mentioned in the specification.

The term "derivatives" is extremely broad and encompasses, for example, salt forms, reaction products, and degradation products. Monomeric glucose, and heteropolymers comprising glucose, for example, would qualify as starch derivatives. Yet, applicant provides no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful to form a controlled-release particle with alginate.

Applicant further argues that the reference describes individual derivatives along with their properties (response, p. 6).

Again, this description is of no more help to applicant than the instant specification. Applicant's own reference states that, "Derivatization of starch differs from most chemical modification of polymers in that the changes in properties are attained with very slight changes in the molecule itself." (p. 695 of the reference). This is an important point given applicants amendment regarding solubility. The reference goes on to describe various broad classes of derivatives, which have vastly different properties (particularly those of solubility and form) (see reference pgs. 696-697, which states that certain reagents increase the viscosity, while others reduce the tendency to congeal). Again, no clear direction is provided by the instant specification to show which, if any, of these derivatives is useful in the present invention, or the functional qualities required. Applicant has attempted to define "starch derivatives", after filing the original disclosure, by a property without any discussion of known or disclosed correlation between function and structure of such derivatives, and has presented no evidence that an artisan would have recognized any functional correlation between the

structure of certain starch derivatives and the claimed property. Finally, the submitted reference fails to establish that the skilled artisan would have known that some or any of the starch derivatives described in the particular reference were surely intended by applicant at the time of filing. There is no such nexus in the instant disclosure. Thus, a skilled artisan would not have been apprised of what starch derivatives would be useful in the invention, and applicant has not provided sufficient written description of the broad genus of compounds encompassed by the term "starch derivatives".

Claim Rejections - 35 USC § 112 (2nd Paragraph) (Maintained)

Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 95 recites the limitation, "...wherein dissolved starch granules are formed when the starch complexes with the emulsifier in alkali solution". This limitation is indefinite because it is unclear whether the claim requires the formation of granules or the dissolution of granules. Is the starch dissolved (i.e. granules are absent) or are granules present? If granules are intended to be present the word "dissolved" should be deleted to remove the ambiguity in the claim. This issue has been exacerbated by applicant's amendment that requires the starch emulsifier complex to be at least partially insoluble. It is unclear how the starch granules recited in claim 95 can be both dissolved and at the same time contain an at least partially insoluble starch-emulsifier complex. As applicant points out on p. 8 of the response, "it is impossible to have applicant's partially or completely insoluble

complex and still have a water-soluble material", which is required instant claim 95. Applicant is requested to explain whether the starch granules are dissolved (i.e. soluble) or not (i.e. insoluble). The metes and bounds of the claim are presently unclear.

Response to Arguments

Applicant has not responded to this rejection, thus the rejection is maintained.

Claim Rejections - 35 USC § 102 (Maintained)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by NAKATSUKA (U.S. 4,076,846; Issued Feb. 28, 1978).

1. Nakatsuka discloses edible starch compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising algininate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (col., 15, Table 4, Example 8), reading on claim 121. The particles described in Example 8 comprise casein (i.e. a protein), glycerol, and sorbitol, any one of which qualifies as a bioactive agent per the description of bioactive agents in the instant specification (par. [0039]). In addition to the category of proteins (of which casein is a member), suitable bioactive agents are stated to

include drugs. Both glycerol and sorbitol have been used as laxatives, and thus may fall into the broad category of drugs. Thus, Nakatsuka anticipates claim 122.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Nakatsuka does not anticipate the claimed invention because Nakatsuka teaches a water soluble composition, which applicants assert is excluded by the new limitation "...the starch-emulsifier complex is partially or completely insoluble" (response, p. 7).

It is noted that the instant claims do not recite the solvent in which the starch-emulsifier complex must be partially or completely insoluble. Thus, the compositions of Nakatsuka, which are taught to be water soluble would be insoluble in non-polar solvents, such as lipids and oils, which are used in the art to make the types of feeds instantly claimed. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., partial or complete insolubility in water) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Reciting that the starch-emulsifier complex is partially or completely insoluble *in water* would overcome this rejection.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 87-96, 98, 103, 104, 108-112, 114, 121, and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over KÜRZINGER (U.S. 6,303,175; Issued Oct.

16, 2001) in view of TESTER (WO 99/53902; Published Oct. 28, 1999) and Nakatsuka (of record).

2. Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates (abstract; col. 2, line 65; col. 3, lines 19-25; claims 12 and 13). The preferred feed contains 0.001-50%, of a gel forming compound or compounds that may be alginate in combination with other polymers such as, *inter alia*, starches, cellulose materials, guar gum, or gum arabic (abstract; col. 2, lines 17-26). 0.1-10% of the gel forming component(s) is especially preferred (abstract; col. 1, line 67 to col. 2, line 3; claims 1-5). Examples of the gel forming component(s) present in the range of 1.5-5.5% are provided (col. 3, lines 50-58, Variant 1). These percentages are taught with respect to compositions comprising particular water contents (e.g. 50-99% or 73-94% water) (abstract; col. 2, line 3; col. 3, lines 50-58, Variant 1), and are thus wet weights. Kürzinger specifically teaches that the gel formers can be used alone or preferably in synergistic combinations, improving the acceptance and properties of the feed (col. 2, lines 32-34). Kürzinger teaches the inclusion of emulsifiers such as lecithin for the improvement of consistency and binding of the feed mixture (col. 2, lines 44-50). Kürzinger also teaches that the compositions can be treated by drying (col. 3, lines 19-23). Kürzinger's compositions are intended to be gels that are not soluble in cold water (title; abstract; col. 3, lines 4-6). Thus, the skilled artisan would know that the components thereof should also be insoluble or only partially soluble in water as well.

3. Tester discloses orally administrable compositions comprising alginate and starch for controlled release to the intestine (title; abstract; p. 12, lines 3-6; p. 21, lines

13-17; p. 50, lines 3-7). The compositions can be in the form of granules, tablets, and powders and used in foodstuffs (p. 30, lines 4-9). Tester teaches that the combination of alginate and starch is symbiotic (i.e. synergistic, see p. 31, lines 20-22), each polymer contributing unique characteristics to the composition (e.g. gelling ability (alginate) and active entrapment and digestibility characteristics (starch)) (p. 16, lines 14-25; p. 31, lines 5-22). In particular, Tester teaches that "sodium alginate is a relatively cheap and effective gelling agent. It is symbiotic with starch and forms a coherent matrix" (p. 48, lines 13-15). Thus, the ordinary artisan would have had motivation to specifically select the combination of starch and alginate from the teachings of Kürzinger.

4. Kürzinger does not specify a suitable weight ratio of emulsifier to the non-digestible polymer. The ordinary artisan would have looked to the literature for guidance regarding appropriate amounts of emulsifier to include in the composition.

5. Nakatsuka discloses edible particulate compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising alginate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (col., 15, Table 4, Example 8). Nakatsuka teaches that lecithin is particularly suitable for use with starch materials because it has a desirable affinity toward starch and has an adequate hydrophilic-lipophilic balance (col. 7, lines 59-63). Furthermore, Nakatsuka teaches that up to 10% by weight or more of lecithin can be added, as embodied in examples 7-9 and 20-23 (col. 7, line 65 to col. 8, line 6). Nakatsuka also teaches that a composition containing about 10% by weight lecithin has favorable release properties (col. 7, lines 66-68).

While it is noted that only 1 part by wet weight lecithin is exemplified in examples 7-9, the teaching of up to 10% lecithin is clear, and one of ordinary skill in the art would have recognized the advantages of the release properties in the feed production process as taught by Nakatsuka.

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to utilize from 1% up to 10% wet weight lecithin, in the composition of Kürzinger to provide a particulate feed composition having favorable release properties per the teachings of Nakatsuka. One would have been motivated to do so since Nakatsuka teaches that lecithin is particularly suited to similar feed compositions comprising starch, and since Nakatsuka teaches that such amounts are advantageous. Further, one would have had a high expectation of success in doing so since Kürzinger teaches the use of both starch and lecithin in the feed compositions (col. 2, lines 23 and 50; claim 3).

7. Based on the teachings of Kürzinger the ordinary artisan would have a high expectation of success in combining alginate and any of several non-digestible polymers. The artisan would be guided by Kürzinger's teaching of using a combination of these polymers wherein each could be present in amounts such that the total of the two polymeric components is between about 5.5% and 10% wet weight. Thus, the inclusion of lecithin at the levels taught by Nakatsuka would result in compositions wherein the emulsifier (i.e. lecithin) is present in a ratio of between about 1:2 relative to the non-digestible polymer. It is well within the skill of the ordinary artisan to optimize the precise amounts of these components, particularly given the relatively narrow

teachings of Kürzinger and Nakatsuka. Furthermore, there is nothing of record to show the criticality of the claimed percentage ranges. Therefore, the combination of Kürzinger and Nakatsuka reads on claims 87-95, 103, and 104.

8. As discussed above, under 102 rejections Nakatsuka teaches proteins and other components that qualify as bioactive agents based on the examples provided in the specification. It is noted that the terms "microstructure" and "nanostructure" have not been given special meaning in the specification. Thus, these terms have been interpreted broadly, and encompass the natural feed components disclosed by Kürzinger, such as zooplankton. Furthermore, zooplankton are microbes (i.e. microscopic organisms) (elected species), and are clearly bioactive agents as defined in claim 98. Thus, the combination of Kürzinger and Nakatsuka reads on claim 96 and 98. Both Kürzinger and Nakatsuka disclose compositions comprising glycerol (see col. 2, lines 35-38 of Kürzinger), which is classified by the FDA as a caloric macronutrient, reading on claim 108.

9. While the feed taught by Kürzinger is intended for aquatic animals, the ordinary artisan would readily envisage the possibility of its administration to humans, particularly, in light of Nakatsuka's teaching that the components of the composition should have no harmful effect on the human body (col. 7, lines 41-46). Since many of the species raised in aquaculture are intended for human consumption, the compositions must also be acceptable for human consumption as would be recognized by the ordinary artisan. Thus, the combination of Kürzinger and Nakatsuka renders claim 109 obvious.

10. As noted *supra*, the feed taught by Kürzinger is for aquatic animals, especially fish, shrimp, and invertebrates (abstract). Further Kürzinger teaches the use of the disclosed feed for ornamental fish in an aquarium (i.e. domestic animals). Since Nakatsuka teaches that the components of the composition should have no harmful effect on the human body, one of ordinary skill in the art would readily have envisioned humans as a target animal for the feeds of the invention, particularly since many of the aquaculture species for which these feeds are intended are raised for human consumption, either directly or indirectly. Thus, the combination of Kürzinger and Nakatsuka renders claims 110-112 and 114 obvious.

Response to Arguments

While applicant's arguments are moot in light of the new rejections set forth herein, some of applicant's arguments are addressed herein to clearly set forth the Office's positions. Applicant argues that it would not have been obvious for the skilled artisan to select alginate and starch from the gel formers taught by Kürzinger (response, p. 8).

In addition to the teachings of Nakatsuka presented in the prior Office Action, which were ignored by applicant in the response, Tester is cited herein solely to provide applicant with a more complete picture of the prior art. The skilled artisan would have clear motivation to select the required components given the teachings of the prior art. No impermissible hindsight has been used.

Applicant argues that the term "complex" has been defined in the instant specification, and refer to par. [0054] of the specification (response, p. 8).

In contrast to applicant's incorrect assertion, paragraph [0054] describes the properties of the complex (i.e. solubility), but fails to define the term "complex" itself.

Applicant argues that Nakatsuka, the secondary reference, teaches away from the recited partially or completely insoluble complex (response, p. 8).

However, Nakatsuka does not "teach away" from Kürzinger. First, it is not Nakatsuka, but rather Kürzinger (the primary reference) that is being modified. Kürzinger teaches gelled formulations (i.e. partially or completely insoluble). Applicant is reminded that Kürzinger teaches all of the structural components claimed, and Nakatsuka and Tester are merely relied upon for motivation and teachings of certain amounts of components, about which Kürzinger is silent. Second, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Kürzinger teaches all of the structural limitations required by the claims.

Applicant argues that if Kürzinger intended the feed to be insoluble, then Nakatsuka, teaches away from Kürzinger (response, p. 8).

This argument is analogous to that presented in response to the prior Office Action, that there is no suggestion to combine Kürzinger and Nakatsuka.

Both Kürzinger and Nakatsuka are concerned with similar problems in the art. Specifically, Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates and Nakatsuka discloses edible particulate compositions for

use in feedstuffs, agriculture, and fisheries. By applicant's own admission both references are concerned with molded feed compositions. Thus, there is sufficient motivation for a skilled artisan to look to both of the cited references. Nakatsuka establishes amounts and motivation for the particular components in Kürzinger, and there is no "teaching away" by combining these references. In response to applicant's argument that all the properties of Nakatsuka cannot be bodily incorporated into Kürzinger, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). A *prima facie* case of obviousness has been established.

Claims 87, 97-100, 103, 105-107, 113, 115, 116, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger in view of Nakatsuka as applied to claims 87-96, 98, 103, 104, 108-112, and 114 above, and further in view of VILLAMAR (WO 02/00035; published Jan. 3, 2002).

11. The teachings of Kürzinger and Nakatsuka have been presented *supra*. It is noted that applicant has defined "controlled release" delivery systems to include systems manipulated to assure that the materials within a particle are delivered intact to the desired location (paragraph [0046]). Based on this definition, the particles of Kürzinger also provide controlled release since they allow the materials within the particles (i.e. the natural feed components) to be delivered intact to the desired location,

that being the stomach of the animal. Additionally, Kürzinger teaches the use of a variety of natural feed components, but does not explicitly teach the inclusion of the microbes recited in claims 99-100. Kürzinger does not teach the particle sizes recited in claims 105 and 106 and does not teach bioattractants.

12. It is noted that alginate-containing beadlets and particles for aquaculture use are well known in the art and many are used as controlled release compositions. For example, Villamar discloses a bioactive food complex in the form of particles or microcapsules that comprise alginate and other non-digestible polymers as well as emulsifiers such as lecithin (p. 10, 2nd and 3rd paragraphs; p. 14, 3rd paragraph; p. 16, 2nd paragraph). These feed particles serve to deliver different bioactive components to the digestive tract (such as the intestines) of animals such as shrimp or fish or other livestock raised commercially to control bacterial disease in such livestock (abstract, p. 7, 2nd paragraph). Thus, the compositions of Villamar are controlled release compositions for the bioactive agent(s) incorporated therein. Villamar teaches the inclusion of probiotic bacteria in the compositions of the invention (abstract), and teaches that *Bacillus* sp., *Lactobacillus* sp., and other bacteria are probiotics commonly added to feeds in the animal agriculture industry (p. 6, last paragraph). Villamar specifically teaches the use of, *inter alia*, *Bacillus subtilis*, *Bacillus licheniformis*, and *Lactococcus lactis* (p. 6, 3rd paragraph; claim 6).

13. One of ordinary skill in the art would recognize that the animal agriculture industry includes such feedstock animals as mollusks, rotifers, and artemia. Furthermore, Villamar teaches adjusting the size and shape of the bioactive food

complex to complement the feeding mechanism and behavior of the aquatic animal target species (p. 17, 1st and 2nd paragraphs). In particular, Villamar teaches the production of particles in the size range of about 20-200 μm for small/larval animals and particles from about 100-1000 μm for larger/postlarval animals. Villamar also teaches the use of bioattractants (p. 11, top paragraph), rendering claim 123 obvious.

14. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include known probiotic bacteria such as *Bacillus* spp. in the compositions of Kürzinger. One would have been motivated to do so since Villamar teaches that probiotic bacteria are advantageous for controlling bacterial disease in aquaculture. Based on Villamar's teachings, it also would have been *prima facie* obvious to adjust the particle size of the compositions (including particles of about 150 μm) and include a bioattractant as needed to feed any cultivated aquatic animal, as would be recognized by the ordinary artisan. Further, one would have had a high expectation of success in doing so since the compositions of Villamar comprise alginate, other non-digestible polymers, and lecithin as do those of Kürzinger. Thus, the combination of Kürzinger, Nakatsuka, and Villamar renders obvious claims 87, 97-100, 103, 105-107, 113, 115, and 116.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicant argues that Villamar does not teach the inclusion of starch in the disclosed feed particles for commercially raised livestock such as shrimp or fish (response, p. 9).

Applicant appears to be suggesting that references are not combinable unless

each teaches exactly the same invention. This is clearly not the standard for obviousness. Villamar does not need to teach the inclusion of starch, as this is taught by Kürzinger (and Nakatsuka and Tester). The combination of Kürzinger, Nakatsuka, and Tester teaches or suggests each element of the instant claims.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

Claims 87-100, 103-116, and 121-123 are rejected. Claims 1-86 are cancelled.
No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-

Art Unit: 1611

5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kevin S Orwig/

/David J Blanchard/
Primary Examiner, Art Unit 1643